Supporting Statement For

Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program
0910-0569

A. JUSTIFICATION

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Attachment A) (MDUFMA) (Public Law 107-250) amends section 704 of the Federal Food, Drug, and Cosmetic Act (the act) by adding subsection (g). (21 U.S.C. 374(g)). This amendment authorizes FDA to establish a voluntary third party inspection program applicable to manufacturers of Class II or Class III medical devices who meet certain eligibility criteria. Under this new Inspection by Accredited Persons Program (AP Program), such manufacturers may elect to have third parties that have been accredited by FDA (accredited person or AP) conduct some of their inspections instead of FDA.

The FDA is announcing the availability of the final guidance entitled "Requests for Inspection by an Accredited Person under the Inspections by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002" .

1. Circumstances Making the Collection of Information Necessary

The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

The new program will allow manufacturers greater control over the timing of their inspections. In addition, because some of the APs accredited by FDA are already recognized by other countries as persons authorized to conduct inspections of device establishments, it is possible that in some cases a single AP inspection will meet the requirements of more than one regulatory authority, thereby reducing the need for multiple inspections of the same establishment.

FDA requests approval of the following information collection:

Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002

The applicant must submit the following information in support of a request for approval to use an AP

1. Information that demonstrates that the applicant manufactures, prepares, propagates, compounds, or processes" class II or class III medical devices.

2. Information that shows that the applicant markets at least one of the devices in the United States;

3. Information that demonstrates that the applicant markets or intends to market at least one of the devices in one or more foreign countries and **one or both** of the following two conditions are met:

    - One of the foreign countries certifies, accredits, or otherwise recognizes the AP the applicant has selected as a person authorized to conduct inspections of device establishments, or

    - A statement that the law of a country where the applicant markets or intends to market the device recognizes an inspection by the FDA or by the AP.;

4. Information that shows that the applicant's most recent inspection performed by FDA, or by an AP under this program, was classified by FDA as either "No Action Indicated (NAI)" or "Voluntary Action Indicated (VAI).”; and

5. A notice FDA requesting clearance (approval) to use an AP, identifying the AP the applicant selected.

2. Purpose and Use of the Information

Information from these information collection provisions will be used to determine whether a manufacturer is eligible to participate in the AP program.

3. Use of Information Technology and Burden Reduction

This program allows alternative appropriate technology. Applications and reports can be electronically submitted if the format is approved by FDA.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only Federal agency responsible for the inspection of facilities in which medical devices are manufactured in accordance with the Federal Food, Drug, and Cosmetic Act. Therefore, duplication with other data sources is nonexistent.

5. Impact on Small Business or Other Small Entities

Participation in the AP program is entirely voluntary. As such, there is potentially no impact on small businesses unless they elect to participate in the program.

FDA aids small business by providing guidance and information through the Division of Small Manufacturers Assistance (DSMA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMA provides workshops, on-site evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free "800" telephone number and a website which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

There is no established frequency for the information collection under the third-party review program. Manufacturers may submit requests whenever they wish to use an AP.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.

This regulation is consistent with principles in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In the Federal Register of (June 3, 2004) (69 FR 31397 the FDA requested comments on the information collection (Attachment B). FDA received one comment concerning the potential burden associated with the third party inspectional program application process if related cumulative partial inspections over a two-year period were not recognized by FDA as a single comprehensive inspection. FDA clarified the guidance to state that manufacturers may rely on a single comprehensive inspection or a serious of partial inspections that would cumulatively constitute a complete inspection for the purposes of meeting FDA's biennial inspection requirement. Reapplication to the FDA AP inspection program will not be necessary to conduct each related partial inspection that cumulatively constitutes a single comprehensive inspection of an establishment.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondent

Information regarding APs are available under the Freedom of Information Act and 21 CFR Part 20.

11. Justification for Sensitive Questions.

The information required in a request to use an AP does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

The following is a summary of the estimated annual burden hours for participation in the voluntary program:

Estimated Annual Reporting Burden[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100	1	100	15	1500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The following is an explanation of the burden estimate:

Reporting Burden:

There are approximately 6000 foreign and 9000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible for the AP program. Also 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates that there are 4000 domestic manufacturers and 4000 foreign manufacturers that are eligible for inclusion in the AP program. Based on informal communications with industry, FDA estimates that approximately 100 of these manufacturers may apply to use an AP in any given year.

Costs to Respondents:

For an application for approval to use an AP for an inspection, the total reporting cost to industry is estimated at $2,250 per submission. Approximately 15 hours are required to complete an application. The average to industry per hour for this type of work is $150. The estimated submission cost of $2,250 multiplied by 100 submissions per year equals $225,000, which is the aggregated industry reporting cost.

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

No additional capital or operational expenses are expected as a result of this collection of information.

14. Annualized Cost to the Federal Government

Costs to the government are limited to the time required to review requests for participation in the AP program. FDA estimates that one full time equivalent (FTE) positions consisting of a combination of scientific and engineering professionals and support staff are required for reviewing and processing applications for approval to use an AP for inspections. Based on a cost of $107,000 per position (which is the agency's average cost of an FTE including their benefits), the estimated annual Federal cost is $107,000.

15. Explanation for Program Changes or Adjustments

This is now a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking an exemption of display of effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.

LIST OF ATTACHMENTS:

Attachment A - Section 201 of the Medical Device User Fee and Modernization Act of 2002

Attachment B - Guidance - Requests for Inspection by an Accredited Person under the Inspections by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002

Attachment C - June 3, 2004 Federal Register document - Draft Guidance for Industry, FDA Staff and FDA-Accredited Third-Parties: Requests for Inspection by an Accredited Person under the Inspections by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002; Availability